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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,023	01/13/2004	Babu Mavunkel	219002029210	3276

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EXAMINER

HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,023

Applicant(s)

MAVUNKEL ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/28/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21,23-26,28-32,35,36,39-53,55-57,59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,3-21,23-26,28-32,35,36,39-53,55-57,59 and 60.

DETAILED ACTION

1. Claims 1, 3-21, 23-26, 28-32, 35-36, 39-53, 55-57 and 59-60 are pending in this application.

Application election of Group I, drawn to piperazines on 3/28/2005 is acknowledged.

Upon further review of the case it is deemed necessary to further restrict this case.

Note that effective search could not be accomplished because (1) piperazine is known in the art, (2) the linkers and the non-interfering substituents are not defined, and (3) Ar^2 is very broad in claim 1 and some of the rings recited in claim 9 come ahead of the US classification system before piperazine and require separate searches.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1, 3-21, 23-26, 28-32, 35-36 and 39-53, drawn to piperazine compounds and simple composition where $L^1 = CO$, $L^2 = CH_2$, and $Ar^2 =$ aryl, 5-membered heteroaryl ring (first 9 heteroaryl rings in claim 9), pyridine, indole, benzothiophene, quinoline, isoquinolines, naphthyridine, classified for example in class 544, subclass 360 and 362.
 - II. Claims 1, 3-21, 23-26, 28-32, 35-36 and 39-53, drawn to piperazine compounds and simple composition where $L^1 =$ linker other than CH_2 , $L^2 =$ linker other than CH_2 , and $Ar^2 =$ other heterocyclic rings classified for example in class 544, subclass 235, 238 and 242.

Art Unit: 1624

- III. Claims 55-56, drawn to complex composition, classified in class 514, subclass various.
- IV. Claims 57 and 59-60, drawn to method of treating a condition mediated by p38- α kinase, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Group I and II are drawn to compounds and simple composition of piperazines and is different from Group III that is drawn to complex composition of piperazines. Group I that is drawn to piperazines {where $L^1 = CO$, $L^2 = CH_2$, and $Ar^2 =$ aryl, 5-membered heteroaryl ring (first 9 heteroaryl rings in claim 9), pyridine, indole, benzothiophene, quinoline, isoquinolines and naphthyridines} is different from Group II, since the definition of the linkers and the heterocyclic rings of the Ar^2 are different in Group II. In Group II, the nature of the heteroaryl groups of Ar^2 such as pyrimidines, pyridazines, pyrazines, triazines, quinazolines, quinoxalines is different from the nature of the rings in Group I. Additionally, Group II is different from Group I since the linkers in Group II are not limited to CH_2 and CO . Group III has additional ingredients (corticosteroid, a monoclonal antibody or an inhibitor of cell division) that are not present in Groups I-II. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place. Groups I-III are directed to group of compounds that have different composition and do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. Each group have a different class and subclass

Art Unit: 1624

and are made and used independently of each other and could support separate patents. Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case piperazine containing compounds are useful for the treatment of pain (US Pat. No. 6,784,181) that is different from the utility recited in claim 60.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

If applicants elect Group II, election of a single disclosed species is required.

If applicants elect Group II or Group IV, further restriction may be required.

Advisory Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a**

Art Unit: 1624

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1624

A telephone call was made to Ms. Kate Murashige on May 9, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

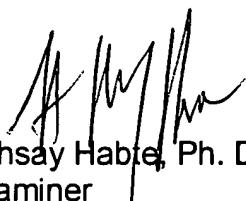
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 10/757,023

Page 7

Art Unit: 1624

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

KH
May 25, 2005